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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/559,583

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Christa Schleper

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EXAMINER

MARVICH, MARIA

ART UNIT

PAPER NUMBER

1633

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/559,583	Applicant(s) SCHLEPER ET AL.	
	Examiner MARIA B. MARVICH	Art Unit 1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) 5-20 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-4 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 02 December 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☒ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>12/2/05</u> . | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Claims 1-20 are pending in this application. However, claims 5-20 have been withdrawn from consideration as they are improper multiple dependent claims as they depend from another multiple dependent claim or depend from claims that depend from multiple dependent claims. See MPEP § 608.01(n). Should applicants amend the claims, consideration will be made as to which claims read on the examined subject matter. Claims 1-4 are under examination.

Information Disclosure Statement

An information disclosure statement filed 12/2/05 has been identified and the documents considered.

Sequence Compliance

This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 for the reason(s) set forth below or on the attached Notice To Comply With Requirements For Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures. Specifically, pages 14, lines 24, 25, 28 and 29 and page 15, lines 7 and 8 contain sequences that are not identified by sequence identifier numbers. If the sequences can be found in the sequence listing it would be remedial to insert the appropriate SEQ ID NO:s. If not, a substitute paper copy of the "Sequence Listing", as well as an amendment directing its entry into the specification,

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CRF and letter stating that the contents of the sequence listing and the CRF are the same and contain no new matter is required. **The nature of the non-compliance did not preclude the examination on the merits of the instant application, the results of which follow.**

Drawings

Figures 2A and 14 are objected to under 37 CFR 1.83(a) because they fail to show any details as described in the specification. Specifically, figure 2A is a photograph of a culture plate. However, the details are indiscernible as the image is too dark. As well, figure 14 comprises a vector with a boxed region, the boxed region is so dark that the writing is illegible. Any structural detail that is essential for a proper understanding of the disclosed invention should be shown in the drawing. MPEP § 608.02(d). A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

Oath/Declaration

The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because: non-initialed and/or non-dated alterations have been made to the oath or declaration. See 37 CFR 1.52(c). Specifically the residence and address of Christa Schleper has been altered without initialing the changes. As well, the last name of Niehaus has been altered with initials.

Claim Objections

Claims 1, 2 and 4 objected to because of the following informalities: claim 1 requires several minor amendments to provide clarity. First, step (b) recites that the vector comprises “the gene encoding the structural proteins and the site-specific integrase of SSV1, SSV2 or pSSVx”. The step does not set forth that the structural protein coding sequences as well as the integrase are from SSV1, SSV2 or pSSVx. As well, it is not clear what is operably linked to the promoters and if the packaging signal is also from SSV1, SSV2 or pSSVx. If all of the components are from SSV1, SSV2 or pSSVx, and comprise promoters, it would be remedial to recite, --the coding sequences for the structural proteins, the coding sequences for the site-specific integrase and a packaging signal from one of SSV1, SSV2 or pSSVx wherein each of the structural protein coding sequences and the site-specific integrase coding sequences are operably linked to expression control sequences--.

Step (d) comprises a multiple cloning site for “insertion go a gene of interest and optionally a 3’ regulatory element”. This has two potential meanings, first that the vector comprises the 3’ regulatory sequence or 2) the cloning site is for the 3’ regulatory element. As it would appear that the later is the case, and to remove any ambiguity as to the claim meaning, it would be remedial to recite --and the vector further comprises an option 3’ regulatory element--.

Claim 2 recites that the origin of replication is selected from one of SSV1, SSV2, pSSVx and pRN plasmids. However, the sequences are from these plasmids but are not

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themselves these plasmids. It would be remedial to amend claim 2 to recite --is an origin of replication from one of--.

Appropriate correction is required.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-4 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. The claims, as written, do not sufficiently distinguish over cells that exist naturally because the claims do not particularly point out any non-naturally occurring products. In the absence of the hand of man, the naturally occurring products are considered non-statutory subject matter. *See Diamond v. Chakrabarty*, 447 U.S. 303, 206, USPQ 193 (1980). The claims should be amended to indicate the hand of the inventor, e.g. by insertion of “Isolated” or “Purified”. Specifically, the vector of claims 1-4 reads on natural SSV1, SSV2, pSSVx and pRN.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-4 are rejected under 35 U.S.C. 102(b) as being anticipated by Stedman et al Genetics **152**: 1397–1405 (August 1999).

Stedman et al teach a vector that comprises the SSV1 genome and hence inherently comprises each of an ori, genes encoding the structural proteins and site-specific integrase from SSV1 each operably linked to expression control sequences. As well, the vector comprise essential genes encoding for example aminoacid biosynthesis genes (see figure 1). Furthermore, the vector has been modified with restriction sites that are flanked by expression control sequences of for example e178 (see figure 5). However, the vector will have natural restriction sites that are found within range of natural promoters.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MARIA B. MARVICH whose telephone number is (571)272-0774. The examiner can normally be reached on M-F (7:00-4:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Woitach, PhD can be reached on (571)-272-0739. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Maria B Marvich, PhD
Primary Examiner
Art Unit 1633

/Maria B Marvich/
Primary Examiner, Art Unit 1633